

**REMARKS**

Claims 15-26 are pending in the application. Claim 15 is an independent claim.

Claims 15 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The rejection proffers that the specification lacks a specific recitation that the detection zone is the last zone that allows liquid transport and that the detection zone is devoid of a binding reagent. The proffer is respectfully traversed.

It is first submitted that both the text of the specification as filed and each of the Figures 1-4 illustrate that the detection zone is the last zone of the element that allows liquid transport. The specification as filed specifically describes that liquid moves through matrix material toward a detection zone, wherein the matrix material is supported on a support material that is not permeable to liquid. In that regard, the Examiner's attention is directed to page 6 lines 26-32 of the specification where it is taught for example, that "absorbent capillary-active material or various absorbent capillary-active material can be arranged on a rigid support material which in turn is not permeable to liquid, does not adversely affect the liquid flow in the matrix material and is inert with regard to the reactions which occur in the analytical element."

Further, each of the Figures, supported by the text of the specification make it clear that the detection zone is the last of the matrix zones on the support and that liquid sample and/or a mixture of liquid sample and elution liquid moves toward the detection zone. In that regard, the Examiner's attention is first directed to page 10 lines 32-33 where it is teaches, "they can be detached by liquid and transported towards the detection zone". Further, at page 12 lines 32-34, it teaches "in order to transport the constituents of the sample, especially the analyte which may be present, with liquid towards the detection zone." Page 13 lines 3-5 of the specification teaches, "This detection complex is transported with the liquid into the detection zone and is determined there". Page 13 lines 5-12 of the specification teaches, "Only if analyte was present in the sample does visually detectable label 2 reach the detection zone in the form of the previously

mentioned complex and can be detected there. If no analyte was present . . . the mixture of conjugates 1 and 2 is bound . . . and no visually detectable label 2 reaches the detection zone". Still further, at page 13 lines 25-27, "If it is intended to transport the sample through the element . . . into the detection zone using an additional elution agent, a kit . . ." Page 14 lines 7-9 teaches that, "elution agent is taken up via the elution agent application zone and migrates through the various zones into the detection zone."

Regarding Figure 1, the specification teaches "a liquid transport path which leads from the sample application zone (1) through the conjugate zone (2) containing conjugate 1 and conjugate 2 and the capture zone (3) containing immobilized analyte or analyte analogue into the detection zone (4). (Column 14 lines 26-31). It is noted that there are only four zones (1-4) illustrated on the support (5). As such, Figure 1 as supported by the text discussing the liquid transport path is sufficient to satisfy the written description requirement in that regard. However, the specification goes further to teach at page 15 lines 17-20 that "as the analyte is transported with liquid through the various zones (1-4). This complex migrates through the capture zone (3) and reaches the detection zone (4)".

This same liquid transport path is taught with regards to Figures 2-4. Specific to Figure 2, it is taught that, "sample is firstly applied to the sample application zone (1). Subsequently sufficient elution agent is applied to the elution agent application zone (6) that analyte is transported into the conjugate zone (2) where it can form a complex with conjugates 1 and 2 and the complex that is formed reaches the detection zone (4) via zone (3) containing immobilized analyte or analyte analogue where the analyte is detected." (Pages 15 last line to Page 16 line 8). It is noted that the sequence of zones (1-4) is the same for Figures 1-2, and 4. (Page 16 lines 15-16). Figure 3 interchanges the sample application zone (1) and the conjugate zone (2), but also teaches the detection zone (4) as being the last matrix zone. (Column 16 lines 15-21). It is noted that in each of the embodiments (Figures 1-4), the detection zone 4 is the last zone of the element that allows liquid transport. Accordingly, it is submitted that both the text of the specification as filed and each of the Figures 1-4 illustrate that the detection zone is the last zone of the element that allows liquid transport.

It is next submitted that the text of the specification as filed provides sufficient written description that the detection zone is devoid of a binding reagent. First, there is no description or suggestion in the text of the specification as filed or in any of the drawings of binding reagent being present in the detection zone. It is noted that in order to detect analyte present in the sample there is no need to incorporate any kind of binding reagent into the detection zone.

The element of the claimed invention does not require binding reagent in its detection zone in order to detect analyte present in the sample. The element of the claimed invention is used for a competitive type assay. In that regard, the Examiner's attention is directed to page 15 first full paragraph of the specification. There it is taught that a detection complex composed of analyte and conjugates 1 and 2 is formed from conjugate zone (2) and migrates through the capture zone (3) and reaches the detection zone (4) where for example a gold label serving as the label 2 is detectable by eye as a red coloration. Due to the above-described liquid transport path, the visually detectable label remains in the detection zone enabling the determination of its presence (since there is no further zone into which the liquid travels).

The rejection notes that the detection zone does not concentrate or absorb all liquid and hold it there. It is important to note that neither concentration nor absorption is required or necessary to the operation of the claimed invention. Rather, the specification teaches, as discussed above, a liquid transport path through zones (1-4). Specifically, the analyte-containing sample moves from the sample application zone (1) to the detection zone (4). The specification provides an example of such transport at page 5 line 29 and page 6 lines 25-28. In that example, the liquid moves by capillary force with absorbent capillary-active material or various absorbent capillary-active materials. By definition, capillary transport will stop once the availability of capillary-active material has ended. Here, Figures 1-4 and the specification teach that the liquid transport path, zones (1-4), ends with the detection zone (4). As such, the journey of the analyte ends in the detection zone.

Next, the rejection proffers that even if it is true that the detection zone is the last zone of the element that allows liquid transport, this zone is still a liquid transport zone and thus would transport liquid away from the detection zone. That proffer is respectfully traversed. Due again to the nature of the liquid transport path, zones 1, 2, 3, and 6 have already been exposed to the liquid sample, before it reaches the detection zone 4. As such, there is no further zone into which the liquid could travel and it remains in the detection zone to carry out the determination of the analyte.

When analyte is present in the sample, the liquid present in the detection zone is a complex of analyte, analyte specific binding partner with first label, and a specific binding partner for the first label carrying a visually detectable label. For example, the visually detectable label is a direct visually detectable label, which can be determined and be correlated to the amount of analyte present in the sample in the detection zone. Any and all sample liquid present in the detection zone will have necessarily passed through zones 1, 2 and 3. Accordingly, if analyte is present, its corresponding visually detectable label will be present in the detection zone to carry out the determination of the analyte.

If no analyte is present in the sample, the complex of analyte-specific binding partner carrying a low molecular weight organic molecule and the specific binding partner for the low molecular weight organic molecule will still form. It will, however, not be able to travel into the detection zone since before the liquid can reach the detection zone; it has to pass the zone (3) where immobilized analyte is present. There, this complex will be captured. So, the visually detectable label will not be present and therefore will not be visible in the detection zone.

Finally, the rejection proffered that "if the capture zone requires a capture reagent immobilized therein to capture the labeled conjugate in order for detection of the label in this area, it is expected that the detection zone would also have such a requirement, otherwise any labels present would diffuse away from the detection zone, rendering detection moot. That proffer is respectfully traversed. The purpose of the capture zone

is not to detect label. Rather, as discussed above, the purpose the capture zone 3 is to prevent travel of the complex of analyte-specific binding partner carrying a low molecular weight organic molecule and the specific binding partner for the low molecular weight organic molecule into the detection zone when no analyte is present in the sample. There is no such capture requirement for the complex of analyte, analyte specific binding partner with first label, and a specific binding partner for the first label carrying a visually detectable label. That complex travels via the transport path into the detection zone where the visually detectable label can be determined and be correlated to the amount of analyte present in the sample in the detection zone.

Accordingly, it is submitted that both the text of the specification as filed and each of the Figures 1-4 illustrate that the detection zone is devoid of a binding reagent. As such, reconsideration of the rejection, leading to its withdrawal and allowance of the claim is respectfully requested.

Claims 15-26 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite. The rejection proffers that claim 15 makes it unclear how the detection zone works.

As discussed above, when analyte is present in the sample, the liquid present in the detection zone is a complex of analyte, analyte specific binding partner with first label, and a specific binding partner for the first label carrying a visually detectable label. The visually detectable label is a direct visually detectable label. As such, it can be determined and be correlated to the amount of analyte present in the sample when present in the detection zone.

The detection zone in the element simply *does not* operate by having binding reagents for the analyte. Instead, the detection zone functions based on the presence or absence of direct visually detectable label in the detection zone. Since the detection zone is the last zone in the element that allows liquid transport, the liquid transport stops once the detection zone is filled with liquid. This means that visually detectable-labeled binding partner that has been bound to an analyte molecule travels to the detection zone, but does

not emerge from it. Accordingly, the direct visually detectable label that reaches the detection zone carries out the determination of the analyte in the detection zone as recited by claim 15.

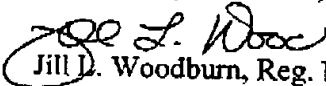
If no analyte is present in the sample, the complex of analyte-specific binding partner carrying a low molecular weight organic molecule and the specific binding partner for the low molecular weight organic molecule will still form. It will, however, not be able to travel into the detection zone since before the liquid can reach the detection zone; it has to pass a zone where immobilized analyte is present. There, this complex will be captured so that no direct visually detectable label will be present in the detection zone and thus no visually detectable label will be visible in the detection zone.

The claim is believed to be sufficiently definite for purposes of 35 U.S.C. 112, second paragraph. Claims 16-26 depend from claim 15. Reconsideration of the rejection leading to its withdrawal is respectfully requested.

The claims as submitted herein are believed to be in condition for allowance, and allowance of the application is respectfully requested. In addition, it is requested that any fees due be charged to Deposit Account Number 50-0877 with reference to (BMID 9941 US).

Respectfully submitted,

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